UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**4:19CR00591 ERW/NAB**
	)	
ABDUL NAUSHAD, M.D., and WAJIHA NAUSHAD,	)	
	)	
Defendants.	)	

INDICTMENT

The Grand Jury charges that:

BACKGROUND

1. At all times relevant to this indictment, defendant Abdul Naushad ("Dr. Naushad") was a medical doctor, licensed to practice medicine in the state of Missouri. Between 2005 and the present, Dr. Naushad has owned and operated a number of pain clinics in Missouri, which clinics operated under the names "Advanced Pain Center" or "Advanced Pain Centers." The clinics were often simply referred to as "APC" and were located in Cape Girardeau, Eureka, Farmington, Festus, Hayti, Kennett, Poplar Bluff, and Sullivan, Missouri. At certain times, Dr. Naushad simultaneously owned and operated as many as six APC clinics in Missouri.

2. At all times relevant to this indictment, defendant Wajiha Naushad was the wife of Dr. Naushad and she and Dr. Naushad jointly managed the above described pain clinics. Among other tasks, Wajiha Naushad was responsible for ordering and managing the use of certain medical devices and drugs at the pain clinics.

The Federal Food, Drug, and Cosmetic Act

3. At all relevant times, the United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting the health and safety of the American public by, among other things, enforcing the provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*. The FDA's responsibilities include regulating the manufacturing, labeling, and distribution of drugs and medical devices shipped or received in interstate commerce to ensure they are safe and effective for their intended uses and the labeling on the drugs and devices contain true and accurate information. It is the responsibility of the FDA to prevent non-FDA approved drugs and medical devices from reaching the marketplace.

FDA Approval Process for Medical Devices

4. The FDCA defines a "device" as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h).

5. A "prescription device" is a device that, because of any potential for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to direct the use of such device. 21 C.F.R. § 801.109.

6. Medical devices are classified into one of three categories, Class I, II, or III. 21 U.S.C. § 360(c). Class III Devices are those that are intended for use in supporting or sustaining life, are of substantial importance in preventing impairment of health, or present a potential unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C). Devices that were first marketed on or after May 28, 1976, are Class III devices by operation of law. 21 U.S.C. § 360c(f)(1). All Class III medical devices must have a FDA Premarket Approval ("PMA"), if not properly exempt from approval. 21 U.S.C. § 351(f)(1)(B).

7. A PMA describes in great detail how the product works, how it was manufactured, and precisely what will be stated on the label and labeling. As part of the process, FDA must approve the manufacturing process, components and ingredients, label and labeling, and packaging set forth in the application. 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20. The approval process requires, among other things, that a manufacturer provide the proposed text of the labeling for the product. 21 U.S.C. § 360e(c)(1)(F); 21 C.F.R. § 814.20(b)(10).

8. The FDCA defines the term "label" as a display of written, printed, or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term "labeling" is broader, and includes all labels, as well as other printed or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. 21 U.S.C. § 321(m).

Prohibited Acts Related to Medical Devices

9. Among other acts, the FDCA prohibits: the receipt in interstate commerce of any drug or device that is adulterated or misbranded and the delivery or proffered delivery thereof for pay or otherwise (21 U.S.C. § 331(c)).

10. Under the FDCA, a device is misbranded if, among other things:

a. its labeling is false or misleading in any particular (21 U.S.C. 352(a));

b. the notice or other information respecting the device was not provided as required under section 510(k) of the FDCA (21 U.S.C. § 360(k) and 21 U.S.C. § 352(o)); or

c. all the words, statements, and other information required by or under authority of the FDCA to appear on the labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; among other things, this means the required information on the labeling must appear in the English language (21 U.S.C. § 352(c); 21 C.F.R. § 801.15(c)(1)).

11. A device is adulterated if, among other things, it is a Class III device pursuant to 21 U.S.C. § 360c(f), and is required under 21 U.S.C. § 360e(a) to have in effect an approved Pre-Market Application for Approval, and does not have such an approval in effect. 21 U.S.C. § 351(f). Orthovisc is a Class III device.

FDA-Approved Orthovisc

12. Orthovisc is a prescription medical device manufactured by ANIKA Therapeutics, which device was approved by the FDA in February 2004 for sale and use in the United States. Orthovisc is a sterile, clear, viscoelastic solution of hyaluronan contained in a single use syringe. Hyaluronan is a natural chemical found in the human body. High amounts of hyaluronan are found in the joint tissues and in the fluid that fills the joints and acts like a lubricant and a shock absorber in the joints. Hyaluronan is needed for joints to work properly.

13. Orthovisc is approved in the United States for patients with osteoarthritic pain in the knees who do not get adequate pain relief from simple pain relievers like acetaminophen or from exercise and physical therapy. In the United States, Orthovisc is injected directly into the

knee joint at intervals prescribed by the treating physician. FDA has only approved Orthovisc for use under the supervision of a licensed practitioner.

14. Orthovisc, which is approved by FDA, will hereafter be referred to as FDA-approved Orthovisc. The label on the FDA-approved Orthovisc box is red, blue and white and the words "ORTHOVISC, HIGH MOLECULAR WEIGHT HYALURONAN" prominently appear on the label.

15. Anika Therapeutics also manufactures a non-FDA approved version of Orthovisc, referred to hereafter as non-FDA-approved Orthovisc or foreign Orthovisc, which may not be used in the United States and may not legally be imported into the United States. The labeling on the foreign Orthovisc is different from the labeling on the FDA-approved Orthovisc. The label on the box containing the foreign Orthovisc has a white background with interlocking blue, yellow, and green rings.

COUNTS 1 to 8

21 U.S.C. §§ 331(c) and 333(a)(2)
and 18 U.S.C. § 2
Receipt or Delivery in Interstate Commerce of an Adulterated Device with the Intent to Defraud

16. The allegations contained in paragraphs 1 through 15 of this Indictment are re-alleged and incorporated by reference as if fully set out herein.

17. In or about February, 2007, CP Logistics shipped hyaluronic acid sodium to the Advanced Pain Center in Popular Bluff, Missouri. On February 7, 2007, the FDA, New York District Office, sent a "Notice of FDA Action" to the clinic, advising that the hyaluronic acid sodium was refused admission into the United States because the hyaluronic acid sodium "appears to be a new drug without an approved new drug application. Drug is available in the

U.S. and therefore not permitted under the personal use exemption. Almost all drugs are considered new drugs. . . .The U.S. Customs Service will cause the entire shipment to be returned to the sender or destroyed if the sender is unknown."

18. Subsequent to the 2007 FDA notice to APC, the defendants continued to order non-FDA approved drugs and devices from foreign companies. From at least as early as 2011, the defendants ordered foreign Orthovisc, but caused it to be shipped in interstate commerce to their residence in St. Louis County, Missouri, instead of having it shipped to one of their several Advanced Pain Centers. The defendants did this to reduce the likelihood that others would discover that they were illegally buying foreign Orthovisc. After receiving the foreign Orthovisc, the defendants would then personally deliver the foreign Orthovisc to the APC clinics, where APC doctors and advanced nurse practitioners injected the foreign Orthovisc into patients' knees and billed health care insurers for the foreign Orthovisc.

19. From in or about 2007 to in or about 2016, the defendants purchased foreign Orthovisc online from a company called Willow Creek Enterprises Limited ("Willow Creek"). During this period, the defendants did not purchase any FDA-approved Orthovisc, although it was readily available in the United States.

20. From the documents the defendants received from Willow Creek, the defendants knew the Orthovisc that they purchased from Willow Creek was shipped into the United States from outside the country. The Willow Creek packing slips and invoices, which the defendants received with the foreign Orthovisc, identified Willow Creek as a company located in Canada.

21. According to Willow Creek emails, Willow Creek obtained at least some of the foreign Orthovisc, purchased by the defendants, from a company called World Medical Ltd, which is incorporated in England. The lot number of some of the foreign Orthovisc, purchased

by the defendants, indicate that the foreign Orthovisc in that lot was to be sold in one or more of the following countries: Austria, Croatia, Cyprus, Egypt, Germany, Hungary, Iraq, Italy, Malaysia, Oman, Philippines, Portugal, Singapore, Spain, United Kingdom, and the United Arab Emirates.

22. The foreign Orthovisc was shipped by Parcel Force and delivered by the United States Postal Service ("USPS") to the defendants' home. On several occasions, defendant Wajiha Naushad personally accepted and signed for the receipt of the foreign Orthovisc delivered to her home.

23. Dr. Naushad received Willow Creek invoices, reflecting a purchase price of between $37.00 and 55.00 per unit for the foreign Orthovisc, which is less costly than a unit of FDA-approved Orthovisc. The defendants paid Willow Creek with checks drawn on a Heartland or Midland Bank account (# 4176) and a Bank of America account (#0160), in the name of Advanced Pain Centers. Dr. Naushad's name is listed on the "AUTHORIZED SIGNATURE" line on the checks, which were often in the amount of $4500.00 or $4950.00.

24. On some occasions, Dr. Naushad personally injected or supervised the injection of the foreign Orthovisc into patients at the APC clinics. The defendants did not inform the patients that they were receiving a non-FDA-approved medication. Nor did the patients receive any financial benefit or discount from the defendants' use of the foreign Orthovisc. The defendants were the only ones to financially benefit from using the foreign Orthovisc.

25. Between in or about 2007 to in or about 2016, the defendants caused hyaluronic acid sodium and foreign Orthovisc, neither of which was FDA approved, to enter into interstate commerce.

26. On or about the dates indicated below as to each count, in the Eastern District of Missouri, and elsewhere,

ABDUL NAUSHAD, M.D.,
and
WAJIHA NAUSHAD,

the defendants herein, did, with the intent to defraud and mislead, receive and cause to be received a device, specifically Orthovisc, into interstate commerce that was adulterated within the meaning of 21 U.S.C. 351(f)(1)(B) and delivered and caused the delivery and proffered delivery of such device for pay or otherwise:

COUNT	DATE OF DELIVERY	DEVICE
1	July 24, 2014	Orthovisc, 90 filled syringes
2	October 6, 2014	Orthovisc, 90 filled syringes
3	August 12, 2015	Orthovisc, 90 filled syringes
4	December 30, 2015	Orthovisc, 135 filled syringes
5	March 25, 2016	Orthovisc, 90 filled syringes
6	July 1, 2016	Orthovisc, 90 filled syringes
7	July 20, 2016	Orthovisc, 90 filled syringes
8	November 21, 2016	Orthovisc, 90 filled syringes

All in violation of Title 21, United States Code, Sections 331(c), 333(a)(2); and Title 18 United States Code, Section 2.

COUNT 9

Smuggling goods into the United States
18 U.S.C. §§ 545 and 2

27. The allegations contained in paragraphs 1 through 25 of this Indictment are re-alleged and incorporated by reference as if fully set out herein.

28. From in or about July 2014 to in or about November 2016, in the Eastern District of Missouri and elsewhere,

ABDUL NAUSHAD, M.D.,
and
WAJIHA NAUSHAD,

the defendants herein did receive, sell, and facilitate the transportation and sale of merchandise, to wit: the prescription device Orthovisc, after importation, and knowing the same to have been brought into the United States contrary to the prohibition against introducing devices that were adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) into interstate commerce, in violation of 21 U.S.C. § 331(c).

All in violation of Title 18, United States Code, Sections 545 and 2.

COUNT 10

Smuggling goods into the United States
18 U.S.C. §§ 545 and 2

29. The allegations contained in paragraphs 1 through 25 of this Indictment are re-alleged and incorporated by reference as if fully set out herein.

30. From in or about July 2014 to in or about November 2016, in the Eastern District of Missouri and elsewhere,

ABDUL NAUSHAD, M.D.,
and
WAJIHA NAUSHAD,

the defendants herein did receive, sell, and facilitate the transportation and sale of merchandise, to wit: the prescription device Orthovisc, after importation, and knowing the same to have been brought into the United States contrary to the prohibition against introducing devices that were misbranded within the meaning of 21 U.S.C. § 351(f)(1)(B) into interstate commerce, in violation of 21 U.S.C. § 331(c).

All in violation of Title 18, United States Code, Sections 545 and 2.

COUNTS 11 to 21

Health Care Fraud Scheme
18 U.S.C. §§1347(a)(1) and 2

31. The allegations contained in paragraphs 1 to 25 of this Indictment are re-alleged and incorporated by reference as if fully set out herein.

32. Dr. Naushad has been an approved Medicare and Medicaid provider since October 2002. At times, Dr. Naushad has also been a provider for or has submitted reimbursement claims to other health care benefit programs, including Tricare and private health insurance companies.

Relevant Medicare Provisions

33. The Medicare Program is a federal health benefits program which the United States Department of Health and Human Services (HHS) administers through the Centers for Medicare and Medicaid Services (CMS). Medicare Part B reimburses health care providers for covered health care services provided to eligible elderly and disabled patients in outpatient settings. Medicare will only reimburse health care providers for drugs or medical devices that the FDA has approved.

34. CMS acts through fiscal agents, called Medicare Administrative Contractors ("MAC"), which are agents of CMS for Medicare Part B. The MACs are private entities, such as insurance companies, that review claims and make payments to health care providers for services rendered to Medicare beneficiaries. Wisconsin Physicians Service Insurance Corporation ("WPS") is the MAC for Eastern Missouri and thus processes reimbursement claims submitted by Advanced Pain Centers.

35. To receive Medicare reimbursement, physicians and other qualified health care providers must execute a written provider agreement. The provider agreement obligates the health care providers to know, understand, and follow all Medicare regulations and rules.

36. As part of the application process, Dr. Naushad signed a CMS-8551 form that informed him of the penalties for falsifying information to gain or maintain enrollment in the Medicare program and of the penalties for falsifying information when seeking reimbursement from the Medicare program. Under Section # 14, entitled "Penalties for Falsifying Information," the Medicare provider agreement states:

> 18 U.S.C. 1035 authorizes criminal penalties against individuals in any matter involving a health care benefit program who knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact; or makes any materially false, fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for health care benefits, items, or services. . . .
>
> 18 U.S.C. 1347 authorizes criminal penalties against individuals who knowing[ly] and willingly execute or attempt, to execute a scheme or artifice to defraud any health care benefit program, or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by or under the control of any health care benefit program in connection with the delivery of or payment for health care benefits, items, or services. . . .

37. The provider agreement signed by Dr. Naushad also contained a "Certification Statement," (Section #15) that provided in part: "I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity." Dr. Naushad signed provider agreements containing the sections entitled "Penalties for Falsifying Information" and "Certification Statement" on four separate occasions: September 20, 2006; July 27, 2009; January 12, 2010; and May 18, 2010.

38. After the successful completion of the application process, Dr. Naushad was assigned a unique provider number, which is a necessary identifier for billing services to Medicare. Additionally, Dr. Naushad was provided access, at no cost, to regulations and other materials governing Medicare reimbursement.

39. Medicare providers must retain medical records for the length of time required by state law or five years from the date of discharge if there is no requirement in state law. Missouri statutes require that physicians maintain patient records for a minimum of seven years from the date when the last professional services were rendered.

Relevant Medicaid Provisions

40. In addition to being a Medicare provider, at all relevant times, Dr. Naushad was enrolled in the Missouri Medicaid Program, which HHS, through CMS, administers at the federal level. The Medicaid Program is a federal and state funded program that reimburses health care providers for health services provided to eligible low income individuals. The Missouri Medicaid Program, now called MO HealthNet, is administered by the Missouri Department of Health and Human Services.

41. A Medicaid provider must enter into a written agreement with MO HealthNet to receive reimbursement for medical services provided to Medicaid recipients and must agree to abide by MO HealthNet's regulations in rendering and billing for those service.

Description of Health Care Fraud Scheme

42. It was part of a scheme and artifice to defraud health care benefit programs that from in or about 2007 to in or about 2016, the defendants purchased foreign, non-FDA-approved medical devices, including hyaluronic acid sodium and foreign Orthovisc, from foreign countries and thereby caused it to be illegally imported into the United States.

43. It was further part of the scheme and artifice to defraud that the defendants concealed the illegal purchases of Orthovisc from the FDA, Medicare, Medicaid, and other regulatory agencies. Moreover, the defendants did not inform their patients nor disclose on the informed consent forms that foreign, non-FDA approved Orthovisc was to be injected into their bodies.

44. It was further part of the scheme and artifice to defraud that from in or about 2011 to in or about 2017, the defendants submitted, or caused to be submitted, reimbursement claims to insurers which falsely and fraudulently represented that the patients identified in the claims received FDA-approved Orthovisc, when the defendants knew the patients had received non-FDA-approved Orthovisc and further knew that the insurers would not pay for non-FDA-approved drugs or devices.

45. It was further part of the scheme and artifice to defraud that the defendants used or caused to be used CPT code J7324 on reimbursement claims to mislead and deceive insurers into believing that FDA-approved Orthovisc was provided to patients. CPT code J7324 is the alpha-numeric code used by health care providers to request reimbursement from insurers for Orthovisc injections.

46. On or about the dates indicated below, in the Eastern District of Missouri,

ABDUL NAUSHAD, M.D.,
and
WAJIHA NAUSHAD,

the defendants herein, knowingly and willfully executed and attempted to execute, the above described scheme or artifice to defraud the Medicare and Medicaid Programs, health care benefit programs, in connection with the delivery and payment for health care benefits, items, and services, that is, the defendants submitted, and caused the submission, of reimbursement claims

to health care benefit programs, for misbranded and adulterated medical devices, to wit, non-FDA approved Orthovisc:

COUNT	PATIENT	DATE OF SERVICE	DATE CLAIM SUBMITTED	CPT CODE ON CLAIM	INSURER
11	A.E.	3/23/2017	4/3/2017	J7324	Medicare
12	D.B.	12/31/2015	1/31/2016	J7324	Medicare
13	D.B.	2/25/2016	3/4/2016	J7324	Medicare
14	D.H.	8/24/2015	9/2/2015	J7324	Medicare/Medicaid
15	M.G.	6/17/2016	6/28/2016	J7324	Medicare/Medicaid
16	M.G.	7/1/16	7/12/16	J7324	Medicare/Medicaid
17	M.G.	7/22/2016	7/29/2016	J7324	Medicare/Medicaid
18	S.M.	6/3/2016	6/13/2016	J7324	Medicare/Medicaid
19	S.M.	6/17/2016	6/24/2016	J7324	Medicare/Medicaid
20	T.M.	10/26/2016	2/14/2017	J7324	Medicare
21	T.M.	11/30/2016	1/6/2017	J7324	Medicare

All in violation of Title 18, United States Code, Section 1347(a)(1) and Section 2.

FORFEITURE ALLEGATION

The Grand Jury further finds by probable cause that:

1. Pursuant to Title 18, United States Code, Section 982(a)(7), upon conviction of an offense in violation of Title 18, United States Code, Sections 1347 as set forth in Counts 11 through 21, the defendants shall forfeit to the United States of America any property, real or personal, that constitutes or is derived from gross proceeds traceable to the commission of the offense.

2. Pursuant to Title 18, United States Code, Section 982(a)(7) and 28 United States Code, Section 2461, upon conviction of an offense in violation of Title 21, United States Code, Section 331 and Title 18, United States Code, Section 545 as set forth in Counts 1 through 10, the defendants shall forfeit to the United States of America any property, real or personal, that constitutes or is derived from gross proceeds traceable to the commission of the offense.

3. Subject to forfeiture is a sum of money equal to the total value of any property, real or personal, constituting or derived from any proceeds traceable to said offense.

4. If any of the property described above, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty,

the United States of America will be entitled to the forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p).

A TRUE BILL.

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FOREPERSON

CARRIE COSTANTIN
Attorney for the United States
Acting Under Authority
Conferred by 28 U.S.C. § 515

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DOROTHY L. McMURTRY, #37727MO
Assistant United States Attorney